



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL - 2 1999

6539 '99 JUL -6 P1:40

Ms. Janice R. Olch
4390 W. Red Mountain Road
Bisbee, Arizona 85603

Dear Ms. Olch:

Thank you for your recent inquiry to Senator John McCain, regarding actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation. Senator McCain has asked us to respond directly to you.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients" FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR has been extended to July 19, 1999.

98N 1038

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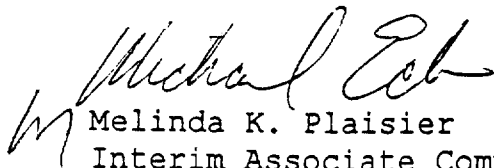
Page 2 - Ms. Janice R. Olch

We have forwarded your correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of irradiated foods will take into account all of the data and information received.

In regard to irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns.

Sincerely,

A handwritten signature in cursive script, appearing to read "Melinda K. Plaisier".

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosures

cc: The Honorable John McCain
United States Senate
Washington, D.C. 20510-0303

Dockets Management Branch ✓
(98N-1038)

JOHN McCAIN

ARIZONA

CHAIRMAN, COMMITTEE ON COMMERCE,
SCIENCE, AND TRANSPORTATION

COMMITTEE ON ARMED SERVICES

COMMITTEE ON INDIAN AFFAIRS

United States Senate

May 26, 1999

Ms. Diane Thompson
Legislative Affairs
Food and Drug Administration
5600 Fishers Lane, Room 15-55
Rockville, Maryland 20857-0001

Dear Diane:

I have enclosed inquiries which I have received from several of my constituents from Arizona.

I would greatly appreciate it if you would review this material within existing rules, regulations and ethical guidelines. Please send a prompt response addressing this issue to each of these constituents, and provide me with copies of the responses for my records.

PLEASE SEND THE COPY TO THE ATTENTION OF: Brian Roth in my Washington office, 241 Russell Senate Office Building, Washington, D.C. 20510. Thank you very much for your kind assistance and cooperation.

Sincerely,



John McCain
United States Senator

JM/ina
Enclosures

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TELEPHONE FOR HEARING IMPAIRED
(202) 224-7132
(602) 952-0170

No. 99-3756

L. 11123

J. 1112

Janice R. Olch
4390 W. Red Mountain Road
Bisbee, Arizona 85603

May 7, 1999

Senator John McCain
241 Russel Senate Office Building
Washington, DC 20510

Dear Senator McCain:

I'm enclosing a copy of my comments submitted to the FDA regarding labeling requirements for irradiated foods which are currently under review.

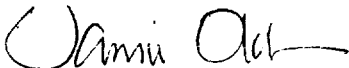
Food irradiation is a quick and temporary fix for poor food production sanitation and a way of disposing of nuclear wastes by selling them to private industry and leaving the taxpayers to fund the inevitable clean-up costs. According to a poll conducted by CBS in 1997, 77% of consumers do not want irradiated foods. It is completely unethical to impose irradiation on consumers who do not want it in order to protect factory-farmers from the consequences of their business practices.

It is your responsibility to represent the best interests of your constituents. Since the use of irradiation in food production, processing, and handling is untested at best, and in the worst case hazardous to consumers, I urge you to support the maintenance of the FDA's current labeling requirements of all irradiated foods and all foods containing irradiated ingredients. The requirements should be maintained and they should not be permitted to expire.

As a homemaker, I am determined to offer my family only the safest foods. I will not purchase and will not allow my family to eat irradiated foods in any form until the effect of long term ingestion of the foods on human health has been studied and the safety of irradiated foods has been confirmed. If I cannot stop this latest assault on the integrity of our food supply, I should at the very least have the ability to identify what processes my foods have been subjected to through clear and prominent labeling, and the right to choose other, non-irradiated foods.

Please support my right to choice.

Sincerely,



Janice Olch

Janice R. Olch
4390 W. Red Mountain Road
Bisbee, Arizona 85603
(520)366-5641 email <riovista@primenet.com>

May 7, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-1038, Irradiation in the Production, Processing, and Handling of Food

To whom it may concern:

The FDA should retain the current labeling law, the current terminology of "treated with irradiation" or "treated with irradiation," and the use of the radura symbol on all irradiated foods. The label should be large enough to be readily visible to the consumer and should be placed on the front of the package. The label contains important information regarding the processing of the contents and therefore deserves a prominent place on the packaging. For unpackaged whole foods such produce, this information should be clearly displayed on a poster in plain view and adjacent to where the product is displayed for sale.

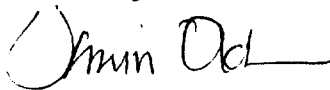
Like any other label, irradiation labels are required by the FDA to be truthful, not misleading. I believe that the alternative terms "electronic pasteurization" or "cold pasteurization" are misleading because pasteurization is an entirely different process of heating and cooling.

In it's initial petition, the FDA concluded that irradiation was a "material fact" about the processing of food and therefore should be disclosed. The material fact remains, therefore the labeling requirement should remain. Irradiation alters the nutrients in food, causes changes in sensory and storage characteristics, and causes chemical changes in food that may be hazardous. Consumers have a right to know if this process has been used on their food.

The requirement of irradiation exposure should not expire. If some consumers become familiar with the radura, there will always be new consumers, young people, immigrants, entering the marketplace who will not be. Also, because of the newness of the technology and the need to assess the public health effects of ingesting irradiated foods, I believe the FDA's labeling requirements should not be permitted to expire.

I urge you to place the comments received on the Internet so that the public can be informed about who is participating in this comment process.

Sincerely,



Janice Olch

cc: Representative Jim Kolbe
Senator Jon Kyl
Senator John McCain